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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/006,869	12/03/2001	Orest W. Blaschuk	100086.407C7	1299

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EXAMINER

MORAN, MARJORIE A

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 05/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/006,869	<b>Applicant(s)</b> BLASCHUK ET AL.	
	<b>Examiner</b> Marjorie A. Moran	<b>Art Unit</b> 1631	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 February 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 8 and 105-117 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 8 and 105-117 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)     | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

***Election/Restrictions***

Claims 8 and 105-117 are pending. SEQ ID NO: 910 was elected in response to the restriction requirement of 4/30/03. It is noted that this was a restriction requirement, as elucidated in the last office action, and not an election of species.

All SEQ ID NO's other than SEQ ID NO: 910 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected sequences, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 13.

An action on the merits of claims 8 and 105-117, ONLY as they read on elected SEQ ID NO: 910, follows. All objections and rejections not reiterated below are hereby withdrawn. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Claim Rejections - 35 USC § 112***

Claims 8 and 105-117 are again rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This is an ENABLEMENT rejection.

Applicant's arguments filed 4/6/04 have been fully considered but they are not persuasive. In response to the argument that the specification teaches that peptides comprising the DAE core sequence are capable of modulating endothelial cell adhesion,

it is again noted that the specification, in fact, discloses a single example wherein a LINEAR sequence, longer than SEQ ID NO: 910 and similar only in comprising the tripeptide DAE, is shown to interrupt cell adhesion. The specification does not provide any evidence anywhere that cyclic peptides comprising DAE Are capable of modulating cell adhesion, nor that SEQ ID NO: 910, whether as a linear or cyclic sequence is known to be capable of modulating cadherin-5- mediated cell adhesion, as now claimed. Binding between a receptor and a ligand is a complex process. As previously set forth, although the sequences disclosed as cadherin-5 CAR sequences MAY be expected to recognize a cadherin, it is not known whether they would all bind to the cadherin, nor if they bind, what the result would be expected to be. It is well known in the art that molecules may bind to a protein without overtly disturbing its activity, or (for a multi-function protein) may affect one function without affecting another. It is not known or disclosed whether the "modulators" listed as cadherin-5 sequences, if they do indeed modulate a cadherin, would be expected to have the same effect on a cadherin. While the tripeptide DAE may be necessary for binding of a ligand to cadherin-5, there is no evidence anywhere that the tripeptide alone is sufficient to (a) bind to cadherin-5, and/or (b) modulate such cadherin-5-mediated cell adhesion. Nor is there any evidence that "any" peptide comprising a DAE motif is capable of modulating such adhesion. The evidence of the specification for a single, linear peptide is not evidence that a general class of peptides (i.e. any peptide of any length) comprising a DAE tripeptide would be expected by one of skill in the art to necessarily modulate cadherin-5-mediated adhesion, nor that a CYCLIC peptide would be expected to do so.

The state of the prior art is such that proteins/peptides comprising SEQ ID NO: 910 are known in the art. The prior art of ROEBROEK et al. (JBC (1992) vol. 267, no. 4, pp. 17208-17215) teaches a subtilisin-type protein from *Drosophila* comprising SEQ ID NO: 910 (residues 968-972) on page 17210, Figure 2. The prior art of CILNIS et al. (Virology (1996) vol. 218, pages 343-351) teaches a variety of viral proteins comprising SEQ ID NO: 910 (residues 285-289) in Figure 1 on page 347. However, the prior art does not teach that these sequences, or any portion thereof, are known to be modulators. The fact that proteins are known in the art which comprise SEQ ID NO: 910 and are NOT known to be modulators indicates a high level of uncertainty in the art as to whether "any" peptide or protein comprising SEQ ID NO: 910 would be reasonably expected to be a modulator.

The level of skill in the art is acknowledged to be high; however, given the lack of teaching in the instant specification for whether SEQ ID NO: 910, or any cyclic peptide, is known to modulate anything, and the high degree of uncertainty indicated by the teachings of the prior art, it would require undue experimentation by one skilled in the art to determine whether, or if, SEQ ID NO: 910 is a modulator of cadherin-5-mediated cell adhesion. One skilled in the art would therefore not know how use SEQ ID NO: 910 as claimed.

For these reasons, and those previously set forth, the rejection is maintained.

### ***Conclusion***

Claims 8 and 105-117 are rejected.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (571) 272-0720. The examiner can normally be reached on Mon. to Wed, 7:30-4; Thurs 7:30-6; Fri 7-1 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571)272-0722. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1631

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marjorie A. Moran  
Primary Examiner  
Art Unit 1631

mam

*Marjorie A. Moran*  
5/3/04